

Applicants : Jan Geliebter, et al.  
Serial No. : 09/531,969  
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#### REMARKS

Claims 50, 54-56, and 59-64 were pending in the subject application. By this amendment, applicants have canceled Claims 50, 54-56 and 59 without prejudice or disclaimer, amended Claims 60-63, and added new Claims 65-68. Accordingly, upon entry of this amendment, Claims 60-68 will be pending and under consideration. The amendment places the application in condition for allowance or in better form for appeal. Applicants maintain that the amendments to the claims do not raise an issue of new matter. Claim 60, as amended, is of similar scope and is supported by Claim 1 as amended in the November 6, 2001 response. The only difference between Claim 60, as amended, and Claim 1 of the November 6, 2001 response, is the elimination of the requirement that the potassium channel regulate the smooth muscle tone. New 65-67 are similar to and are supported by original Claims 2-4. New Claim 68 is supported by previous Claim 60. The claims do not raise issues requiring further consideration and/or search. Accordingly, entry of the amendments is respectfully requested.

#### Rejections under 35 U.S.C. §112, First Paragraph

Claims 50, 54-56, and 59-64 are rejected under the written description and enablement requirements of 35 U.S.C. §112, first paragraph.

Applicants strongly disagree with these rejections for the reasons set forth in applicants' previous responses. Nevertheless, in order to resolve the outstanding issues, applicants have hereinabove canceled Claims 50, 54-56 and 59, which were directed to methods of enhancing relaxation of penile smooth muscle in a subject, thereby rendering these rejections moot with respect to those claims.

The remaining pending claims are all directed to methods of treating a subject, where the claimed method comprises the direct introduction and expression of a DNA

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sequence encoding a potassium channel protein into smooth muscle cells of the subject. Applicants note that these claims are directed to treating a subject and NOT to treating a disease or a disorder. Therefore, whether or not the introduction and expression of a potassium channel can achieve a physiologic effect, or treat a disease or a disorder, is simply not relevant to the enablement of these claims. Applicants submit that the present application provides a written description and an enabling disclosure for these claims.

Numerous support can be found in the application for the method of treating a subject by the introduction and expression of a nucleic acid that encodes a potassium channel protein into smooth muscle cells, as evidenced for example by original Claims 1-4 and 8. The present application teaches that "[g]enes for more than thirty  $K^+$  channels, many of which are expressed in smooth muscle, have been identified." (See, page 27, lines 16-19). Examples of nucleic acid sequences encoding potassium channel protein subtypes were included as an Exhibit in applicants' October 29, 2002 reply. Using the specific teachings of the application, including the teachings of the working examples with DNA encoding maxi-K and  $K_{ATP}$ , the skilled artisan could readily prepare and introduce DNA encoding a potassium channel protein into smooth muscle cells in a subject.

Accordingly, reconsideration and withdrawal of these rejections are respectfully requested.

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CONCLUSIONS

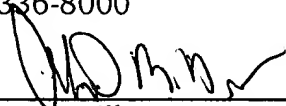
In view of the amendments and remarks made herein above, reconsideration and withdrawal of the rejections in the April 19, 2005 Office Action and passage of the pending claims to allowance are respectfully requested. If there are any minor matters that prevent allowance of the subject application, applicants request that the Examiner telephone the undersigned attorneys.

No fee is deemed necessary in connection with the submission of this reply. However, if there are unanticipated fees required to maintain the pendency of this application, the PTO is authorized to withdraw those fees from Deposit Account 01-1785.

Respectfully submitted,

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May 27, 2005

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